EXHIBIT 7

ORIGINAL

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CITY OF NEW YORK,

Plaintiff,

-against-

THE PURDUE PHARMA COMPANY, PURDUE PHARMA L.P., THE PURDUE FREDERICK COMPANY, PURDUE PHARMACEUTICALS L.P., P.F. LABORATORIES INC., and ABBOTT LABORATORIES,

Defendant(s).

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04 CV 3499

Civil Action No.

COMPLAINT

JURY TRIAL DEMANDED

The City of New York ("the City"), by its attorneys, KIRBY, McINERNEY & SQUIRE, LLP and MICHAEL A. CARDOZO, Corporation Counsel of the City of New York, for its complaint against The Purdue Pharma Company, Purdue Pharma L.P., The Purdue Frederick Company, Purdue Pharmaceuticals L.P., P.F. Laboratories Inc. (collectively "Purdue"), and Abbott Laboratories ("Abbott", collectively with Purdue, the "defendants"), alleges, on information and belief, as follows:

INTRODUCTION

1. The City brings this action to recover unlawful overcharges to the Medicaid program that the City has paid as a direct result of defendants' fraudulent, deceptive and inequitable conduct in procuring patents from the U.S. Patent and Trademark Office ("PTO") for the painkiller OxyContin. Such conduct violated, *inter alia*, Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2, New York General Business Law §§ 340 and 349, and New York Social Services Law § 145-b.

2. The City pays approximately 25% of the costs of all Medicaid expenditures incurred on behalf of City residents, including those for prescription drugs. Medicaid spent more than $5.5 million on behalf of City residents for OxyContin in 2002 alone.

3. OxyContin is a brand name drug, the active ingredient of which is a narcotic substance that relieves a person's pain without causing the loss of consciousness. OxyContin belongs to a class of painkillers known as opioid analgesics. The active ingredient in OxyContin is oxycodone hydrochloride controlled-release ("oxycodone hydrochloride-cr"). Defendants, through intentional fraudulent misrepresentations and material omissions have maintained an unlawful monopoly on oxycodone hydrochloride-cr since 1996, and have charged and reported unlawful monopolistic prices for its OxyContin products.

4. Purdue applied for its original OxyContin patent in 1991 (Patent No. 5,266,331 or "the '331 patent"). Purdue's application for its initial patent was twice rejected. To overcome the objections of the patent examiners, Purdue misrepresented that it had "discovered" facts that allegedly demonstrated OxyContin's effectiveness at low dosages. Purdue's fraud succeeded and the '331 patent issued. In truth, these "facts" existed only in the mind of Purdue's scientists.

5. Purdue continued its fraud when it subsequently applied for Patent No. 5,549,912 (the "'912 Patent"), Patent No. 5,508,042 (the "'042 Patent") and Patent No. 5,656,295 (the "'295 Patent", together with the '912 Patent and the '042 Patent, the "New Patents") in 1996. Each was a continuation of the original '331 patent. Through the issuance of these New Patents, Purdue was able to maintain its unlawful monopoly over OxyCodone hydrochloride-cr.

6. Thereafter, two generic drug manufacturers, Endo Pharmaceuticals, Inc. and Teva Pharmaceuticals Industries, Ltd., applied to the United States Food and Drug Administration ("FDA") for permission to market generic versions of OxyContin. Purdue sued both for patent infringement in this Court. See *Purdue Pharma L.P., et al. v. Endo Pharm, Inc., et al.*, No. 01 Civ. 219 and No. 01 Civ. 8177 (S.D.N.Y.) (the "Endo complaints"); *Purdue Pharma L.P., et al. v. Teva Pharms. U.S.A., Inc.*, et al. No. 01 Civ. 11212; 03 Civ 2312 (S.D.N.Y.) (the "Teva complaints").

7. In response to Purdue's complaints, both Endo and Teva asserted, *inter alia*, that Purdue's '912, '042, and '295 patents were unenforceable due to Purdue's fraudulent and inequitable conduct before the PTO.

8. In June, 2003, Judge Stein of this Court conducted a twenty-day bench trial on the issues raised in the first-filed *Endo* action respecting, *inter alia*, infringement and enforceability of the New Patents.

9. On January 5, 2004, the Court entered an opinion and order declaring the New Patents invalid and unenforceable due to Purdue's fraudulent and inequitable conduct. *Purdue Pharma L.P., et al. v. Endo Pharm., Inc., et al.*, 2004 WL 26523 at *11 (S.D.N.Y. January 5, 2004)

10. Purdue has filed an appeal from this ruling. Teva has filed a motion in its case for summary adjudication of its counterclaims and defenses based on Judge Stein's January 5 opinion and order.

11. As a direct result of defendants' ongoing fraud, the City is and has been forced to pay unlawful monopoly prices, determined by Purdue, for OxyContin prescribed to City residents who receive Medicaid benefits. As of the date of this complaint, no generic

alternatives to the 10, 20, 40 or 160 mg OxyContin products are available. Teva's 80 mg OxyContin product has been available for less than one month.

JURISDICTION AND VENUE

12. This action is brought under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Purdue's violations of the federal antitrust laws, particularly Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2. The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1332, 1337(a), and 15 U.S.C. § 26. 28 U.S.C. §§ 1332 is satisfied because the matter in controversy exceeds $75,000 and the parties are citizens of different states. This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.

13. Venue is proper in this judicial district pursuant to 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) because defendants transact business, are found, and/or have agents in this district and because a substantial portion of the affected trade and commerce described below has been carried out in this district.

14. The illegal monopolization and attempt to monopolize the market for OxyContin and generic versions of OxyContin, as alleged herein, have substantially affected interstate and foreign commerce.

THE PARTIES

15. Plaintiff, the City of New York is a municipal corporation organized pursuant to the laws of the State of New York. By statute, the City pays 25% of Medicaid prescription drug costs. N.Y. Social Services Law §§ 367-a; 368-a. Because of Purdue's fraudulent, deceptive and inequitable conduct, which has prevented generic competition for OxyContin and led to unlawful monopolistic prices for OxyContin, the City has overpaid for OxyContin.

16. Defendant Purdue Pharma L.P. ("Purdue Pharma"), is a corporation organized and existing under the laws of the state of Delaware. Its principal place of business is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut. It is engaged in the business of research, development, manufacture and sale of pharmaceutical products throughout the United States, including in the State of New York. Purdue Pharma owns the New Patents for OxyContin tablets, which have been determined to be frauds on the U.S. Patent and Trademark Office.

17. Defendant the Purdue Frederick Company ("Frederick Co."), is a corporation organized and existing under the laws of the state of New York. Its principal place of business is at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut. It is engaged in the business of research, development, manufacture and sale of pharmaceutical products throughout the United States, including in the State of New York.

18. Defendant the Purdue Pharma Company ("Purdue Co."), is a general partnership organized and existing under the laws of the state of Delaware. Its principal place of business is at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut. Purdue Pharma and Frederick Co. are general partners of Purdue Co. Purdue Co. is engaged in the business of research, development, manufacture and sale of pharmaceutical products throughout the United States, including in the State of New York.

19. Defendant Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals"), is a corporation organized and existing under the laws of the state of Delaware. Its principal place of business is located at 4701 Purdue Drive, Wilson, North Carolina. It is engaged in the manufacturing and formulation of medications for pain relief sold throughout the United States, including in the State of New York.

20. Defendant P.F. Laboratories Inc. ("P.F. Labs") is a corporation organized and existing under the laws of the state of New Jersey. Its principal place of business is located at 700 Union Boulevard, Totowa, New Jersey. It is engaged in the production of pharmaceutical products sold throughout the United States, including in the State of New York.

21. Defendant Abbott Laboratories is headquartered at 100 Abbott Park Road, Abbott Park, Illinois 60064-3500. Abbott is a diversified health care company that discovers, develops, manufactures and markets products and services in the areas of pharmaceuticals, nutritionals, hospital products and diagnostics. In 1996, Abbott entered into an agreement to co-promote OxyContin with Purdue in 1996.

22. Together defendants manufacture and market OxyContin throughout the United States, including in the State of New York.

INTERSTATE TRADE AND COMMERCE

23. During all or part of the relevant time period:

(a) Purdue manufactured, promoted and sold substantial amounts of OxyContin in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States, including in New York City;

(b) Purdue transmitted funds, prices, contracts, bills, and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines (including in New York City) in connection with the sale of OxyContin;

(c) Purdue employed, in furtherance of their unlawful monopolization and attempt to monopolize, as alleged herein, the United States mails and interstate and international telephone lines, as well as means of interstate and international travel;

(d) Purdue used the United States mails and interstate telephone lines to report or cause to be reported false and inflated Average Wholesale Prices ("AWPs") for OxyContin.

RELEVANT MARKET AND DEFENDANTS' MARKET SHARE

24. The relevant product market is the market for the manufacture, use and sale of OxyContin (oxycodone hydrochloride-cr) and all its generic bioequivalents rated "AB" by the United States Food and Drug Administration ("FDA").

25. The relevant geographic market (together with the relevant product market, the "relevant market") is the United States. A nationwide geographic market is appropriate given that (a) the federal government controls the regulatory process for approving drugs for sale in the United States and (b) the marketing, pricing and price reporting, sales and distribution of pharmaceuticals, including OxyContin, occur on a nationwide basis.

26. Defendant Purdue developed and patented, under the '331 Patent, OxyContin as the "first and only 12-hour oxycodone analgesic." OxyContin was said to provide patients with continuous relief from pain over a 12-hour period and reduce pain fluctuations. Because OxyContin requires fewer daily doses, it helps patients adhere to their prescribed regimen more easily and allows them to sleep through the night. OxyContin and generic oxycodone hydrochloride-cr products are not reasonably interchangeable with other analgesics that typically are effective for only four to six hours . OxyContin contains more oxycodone than any drug previously marketed. It is available in 10mg, 20mg, 40mg, 80mg and 160mg. Percocet, the most familiar oxycodone drug, contains only 5mg of oxycodone.

27. At all relevant times, defendants' market share in the relevant product and geographic markets has been 100%. Defendants have controlled 100% of the sales of OxyContin nationwide, including to New York City, by fraudulently obtaining the '331 patent

and the New Patents and by wrongfully enforcing these patents to prevent generic drug manufacturers from creating a competitive marketplace.

FACTUAL ALLEGATIONS

A. The Effect of Generic Drugs on Price

28. Generic drugs are normally priced substantially below the brand-name drugs to which they are bioequivalent. In July 1998 the Congressional Budget Office ("CBO") released a study entitled "How Increased Competition from Generic Drugs Has Affected Prices and Returns In The Pharmaceutical Industry" (the "CBO Study"). The CBO Study concluded that generic drugs save consumers and third-party payors between $8 billion and $10 billion a year. The study involved 21 brand-name prescription drugs that first experienced generic competition between 1991 and 1993. It determined that the generic versions cost initially an average of 25% less than the original brand name drugs at retail prices, and that as the number of generic manufacturers increases, the average prescription price of the generic alternative falls. The CBO's analysis showed that when one to ten firms are manufacturing and distributing generic forms of a particular drug, the generic retail price of that drug averages about 60% of the brand name price. When more than 10 manufacturers have entered the market, the average generic prescription price falls to less than half of the brand-name price.

29. Other studies likewise have concluded that prices of generic drugs decline in response to increased generic competition. For example, economist Richard Caves and colleagues, as cited in the CBO study, found that as the number of generic manufacturers increased from one to 10, the average generic price fell from 60 percent to just 34 percent of the brand-name price. With 20 manufactures, the generic price was only 20 percent of the brand-name price. Since generic prices tend to fall as the number of producers rises, generic manufacturers are most profitable when they are one of the first to enter a market.

30. The July 2002 Federal Trade Commission ("FTC") study "Generic Drug Entry Prior to Patent Expiration" estimates that average drug prices decline some 20% within approximately two years of generic entry. As additional manufacturers bring generic versions of the drug to market, the price continues to drop.

31. The CBO Study also concluded that a brand-name drug loses a significant portion of its market share to generic competitors soon after the introduction of generic competition, even if the brand-name manufacturer lowers prices to meet competition. The study estimated that generic drugs capture at least 44% of the brand-name drug's market share in just the first year of sale.

B. Medicaid Pricing and New York City's Medicaid Obligations

32. Fifty percent of New York City's Medicaid program costs are paid for by the federal government. *See* 42 U.S.C. §§ 1396b(a)(1) & 1396d(b). The remaining 50 percent of costs are generally shared equally by the City and the State. In other words, the City pays 25 percent of most of its Medicaid costs, including the cost of prescription drugs. N.Y. Social Services Law §§ 367-a; 368-a. As required by federal statute, the federal government has expressly approved of New York State's Medicaid program, including the City's payment of a 25% local share. 42 U.S.C. § 1396a(a) and (b), 42 C.F.R. § 433.32 (at 79-29), 42 C.F.R. § 433.33, at 80-84.

33. In 2002, the City's 25% share of Medicaid payments for OxyContin was approximately $1.3 million.

34. Pursuant to New York's Medicaid statute, the City's payments for patented brand-name prescription drugs covered by Medicaid, including OxyContin, are based on the Average Wholesale Price ("AWP") for such drug. New York Social Services Law § 367-a(9). Specifically, brand names drugs for which there is no bioequivalent available (such as

OxyContin given defendants' fraud) and multi-source drugs for which there is no federal upper limit ("FUL") are reimbursed at the rate of AWP minus 12%[1]. N.Y. Soc. Serv. L. §367-a(9)(b)(ii).

35. The AWP for Oxycontin, as for other patented drugs, is not independently determined by Medicaid or the City. Rather, AWPs for OxyContin, or wholesale acquisition costs ("WACs") on which OxyContin AWPs are based, have at all relevant times been self-reported by defendants to various data collection/publishing companies such as Thompson PDR's Pharmacy's Fundamental Reference, the *Redbook*, or First DataBank Inc.'s Annual Directory of Pharmaceuticals and Essential Directory of Pharmaceuticals, the *Bluebook*.

36. Because of their unlawful monopoly in the OxyContin market, and their imposition of unlawful monopolistic prices for OxyContin, *inter alia*, Defendants' AWPs for each dosage of OxyContin were higher than they would have been had defendants' fraud not prevented generic competition. The City overpaid for OxyContin as a result.

37. Defendants knew at all times that their fraudulent AWPs would be relied upon by federal, state and local Medicaid payors, including New York City, in connection with calculating the Medicaid reimbursement for OxyContin.

38. According to the *Redbook*, the AWPs for OxyContin in 2002 were as follows:

[1] The AWP – 12% Medicaid reimbursement formula went into effect May 15, 2003. Previously, and for the majority of the relevant period herein, the reimbursement formula was AWP – 10%.

Dosage Amount	Formulary Code	Reported AWP 2002
OxyContin Tab 10 mg		
25s Each	59011-0100-25	$1.41
100s Each	59011-0100-10	$1.29
OxyContin Tab 20 mg		
25s Each	59011-0103-25	$2.69
100s Each	59011-0103-10	$2.47
OxyContin Tab 40 mg		
25s Each	59011-0105-25	$4.77
100s Each	59011-0105-10	$4.39
OxyContin Tab 80 mg		
25s Each	59011-0107-25	$8.97
100s Each	59011-0107-10	$8.25
OxyContin Tab 160 mg		
25s Each	59011-0109-25	$16.55
100s Each	59011-0109-10	$15.56

39. New York's Medicaid plan requires the utilization of lower cost generic alternatives whenever possible. But for Purdue's fraudulent patent activity, which prevented generic entry to market and permitted Purdue to monopolize the OxyContin market, the price paid by Medicaid for OxyContin would have been lower and the City of New York would have paid less under Medicaid for the drug.

40. The prices that the City pays for Medicaid drugs are also governed by rebate agreements between the federal government and the manufacturers pursuant to 42 U.S.C.

1396r-8(c) and Soc. Serv. L. 367-a(7)(d). The rebate amount is based on the average price for the drug and the best price, defined as the lowest price available from the manufacturer for that drug. By charging and reporting monopoly prices for OxyContin defendants caused a reduction in the amount of the rebate received by the City as a result of these provisions.

C. The Hatch-Waxman Act and Regulatory Scheme

41. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, approval by the FDA is required before a company may begin selling a new drug. Pre-market approval for a new drug, often referred to as a "pioneer" or "brand name" drug, must be sought by filing a New Drug Application ("NDA") with the FDA, demonstrating that the drug is safe and effective for its intended use. New drugs that are approved for sale in the United States by the FDA are typically (but not necessarily) covered by patents, which provide the patent owner with the exclusive right to sell that new or pioneer drug in the Untied States for the duration of the patents involved, plus any extension of the original patent period (the "FDA Exclusivity Period") granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 (the "Hatch-Waxman Act").

42. When the NDA is approved, the FDA lists any patents referenced as part of the NDA application process in a publication known as the Approved Drug Products With Therapeutic Equivalence Evaluations. This publication is commonly called the "*Orange Book*."

43. Once the safety and effectiveness of a new drug is approved by the FDA, it may be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name, which must be dispensed by a licensed pharmacist. The pharmacist must, in turn, fill the prescription with the drug brand specified by the physician, unless an AB-related generic version of that pioneer drug which has been approved by the FDA is available.

44. The FDA views its role in listing patents in the *Orange Book* as "purely ministerial" because it has neither the expertise nor the resources to resolve complex patent coverage issues. 59 Fed. Reg. 50338, 50345 (Oct. 3, 1994). Consequently, the FDA does not scrutinize a party's bases for listing patents in the *Orange Book*, as long as all the information required by statute has been submitted. Should one company challenge the validity of another's *Orange Book* listing, the FDA requests only that the NDA holder provide written confirmation that the patent is properly listed.

45. Congress enacted the Hatch-Waxman Act in 1984 to establish an abbreviated process to expedite and facilitate the development and approval of generic drugs. To effectuate its purpose, the Hatch-Waxman Act permits a generic drug manufacturer to file an Abbreviated New Drug Application (an "ANDA"), which incorporates by reference the safety and effectiveness data developed and previously submitted by the manufacturer of the original, pioneer drug. The Hatch-Waxman Act also provides an economic incentive to the first generic drug manufacturer to file an ANDA for a particular generic drug within a 180-day statutory period of market exclusivity, during which time the initial generic manufacturer has the right to market its drug free from competition from other generic manufacturers.

46. The ANDA must include information concerning the applicant's position vis-a-vis the patent that the pioneer drug manufacturer claims applies to the drug. Therefore, the ANDA filer must provide a certification to the FDA with respect to each such patent.

47. One certification a generic applicant may make is that the patent for the pioneer drug is invalid or will not be infringed upon by the proposed generic company's product (a "Paragraph IV Certification"). Endo and Teva each filed Paragraph IV Certifications with their oxycodone hydrochloride-cr ANDAs.

48. If the ANDA contains a Paragraph IV Certification, the ANDA applicant must provide notice to the owner of each patent that is referred to in the certification, and to the holder of the approved NDA to which the ANDA refers. 21 U.S.C. § 355(j)(2)(B)(I). The notice must include a detailed statement of the factual and legal basis for the ANDA applicant's assertion that the patent is not valid or will not be infringed by the generic product. 21 C.F.R. § 314.95.

49. The brand-name drug patent owner, upon receiving a Paragraph IV Certification from an ANDA applicant, has 45 days to initiate a patent infringement suit against the applicant. 21 U.S.C. § 355(j)(5)(B)(iii). If no action is initiated within 45 days, the process for FDA approval of the generic product is not delayed by patent issues. However, if a patent infringement suit is brought within the 45-day window, FDA approval of the ANDA is automatically postponed until the earliest of the expiration of the patents, the expiration of 30 months from the patent holder's receipt of notice of the Paragraph IV Certification, or a final judicial determination of non-infringement.

50. Accordingly, brand-name drug patent holders need only to file a patent infringement lawsuit within 45 days of receipt of Paragraph IV certification in order to automatically block an ANDA applicant's generic drug from entering the market for up to 30 months. This is precisely what Purdue did with respect to Endo's and Teva's ANDAs.

D. The Threat of Generic Competition in the OxyContin Market

51. Defendants began marketing OxyContin in December 1995. Sales of the drug increased rapidly following its introduction into the marketplace in 1996. According to a 2003 GAO report, by 2001, sales had exceeded $1 billion annually, and OxyContin had become the most frequently prescribed brand-name narcotic medication for treating moderate to severe pain in the United States.

52. OxyContin is Purdue's primary source of earnings. More than 70% of Purdue's 2002 revenue of $1.8 billion came from the sale of OxyContin.

53. In July 2000, Endo filed ANDA 75-923 with the FDA to market generic versions of OxyContin in the 40mg strength. On February 9, 2001 Endo amended its ANDA application to include the 10mg and 20mg strengths of oxycodone hydrochloride-cr. In May 2001, Teva filed ANDA 76-168 and 76-610 to market generic versions of all dosages of OxyContin products.

54. After filing their ANDA applications, Endo and Teva each gave written notice ("notice of certification") to Purdue, pursuant to 21 U.S.C. § 355(j)(2)(B)(i) and (ii), that their ANDAs and the accompanying Paragraph IV certifications had been filed with the FDA. In accordance with 21 U.S.C. § 355(j)(2)(B)(ii), the notices also set forth the legal and factual bases for their claims that the '912, '042 and '295 patents were invalid and/or unenforceable.

E. Purdue's Infringement Actions

55. Within forty-five days of receipt of the notices of certification from both Endo and Teva, Purdue brought suits for infringement of the '912, '042 and '295 patents (hereinafter referred to collectively as the "infringement actions") in the U.S. District Court for the Southern District of New York. The Endo complaints were filed October 20, 2000, March 13, 2001 and August 30, 2001 and styled as *Purdue Pharma L.P., et al., v. Endo Pharmaceuticals, Inc., et al.*, C.A. Nos. 00-CIV-8029, 01-Civ-2109 and 01-Civ-8177. The Teva complaints were filed on September 19, 2001, December 6, 2001 and April 3, 2003, respectively, and styled as *Purdue Pharma LP, The Purdue Frederick Company, the P.F. Laboratories, Inc., The Purdue Pharma Co. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 01-Civ-11212 and No. 03-Civ-2312, respectively.

56. These actions triggered automatic 30-month stays of the FDA's authority to grant final marketing approval to Endo and Teva. The FDA could not grant final marketing approval to Endo's and Teva's ANDAs until the companies prevailed in the infringement actions or until at least 30 months expired, whichever was sooner.

57. By way of defenses and counterclaims Endo claimed that the '912, '042 and '295 patents were invalid, unenforceable and/or not infringed by its formulation of oxycodone hydrochloride-cr tablets, 10mg, 20mg, 40mg and 80mg. Endo also counterclaimed for antitrust damages alleging Purdue breached its duty of candor to, and engaged in inequitable conduct before, the PTO and claiming that Purdue was asserting its right in the New Patents while aware that the New Patents are unenforceable.

58. Teva's defenses and counterclaim were the same as Endo's. Teva asserted likewise that the '912, '042 and '295 patents were unenforceable. Both Endo and Teva also requested declarations that the '912, '042 and '295 patents were unenforceable, and injunctions barring further enforcement of them.

59. On July 31, 2002, the FDA granted tentative approval to Endo's ANDA No. 75-923 for oxycodone hydrochloride-cr Tablets, 10mg, 20mg, 40mg and 80mg. Tentative approval was given to Teva for 80 mg oxycodone hydrochloride-cr on September 29, 2003. By granting tentative approvals to Endo and Teva, the FDA determined that all the criteria for ANDA final approvals had been satisfied except for the resolution of issues relating to patents.

60. Both before and after the New Patents issued, Purdue knew that the New Patents were not enforceable because Purdue and its representatives knowingly had made material misrepresentations to and had concealed material facts from the PTO in connection with the prosecution of the New Patents.

61. Despite this knowledge, Purdue vigorously defended its monopolistic control over the OxyContin markets and charged monopoly prices for its drugs. Purdue commenced, prosecuted, and maintained the sham infringement actions against Endo and Teva and defended against the counterclaims for the improper purpose of maintaining a monopoly in the relevant market, and to conceal by deceit its unlawful monopoly maintenance.

F. The Court Invalidates the '912, '042 and '295 Patents

62. A non-jury trial commenced on June 2, 2003, in the *Endo* matter. Post-trial briefing was completed on August 8, 2003. On January 5, 2004, Judge Sidney H. Stein held that the '912, '042 and '295 patents were invalid and unenforceable because Purdue made material misrepresentations to the PTO.

63. Specifically, the Court determined that upon initial application for the '331 patent, the PTO had rejected Purdue's claim because of its "obviousness" with respect to other existing patents. *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*, 2004 WL 26523, *11 (Jan. 5, 2004), (Stein, J.). In response to the PTO's rejection, Purdue represented to the PTO, *inter alia*, that "it has now been surprisingly discovered" that the oxycodone formulation for the '331 patent "acceptably controls pain over a substantially narrower [range], approximately four fold (10 to 40 mg every 12 hours – around-the-clock dosing) in 90% of patients . . . One skilled in the art would not arrive at this surprising result without the benefit of hindsight." *Id.* Thus, to receive its patents, Purdue represented to the PTO that it had new empirical data showing that 90 percent of chronic pain patients would get relief with low dosages ranging from 10 to 40 milligrams.

64. In fact, Purdue knew when it made these representations to the PTO that it had no proof regarding the effectiveness of the low dosage OxyContin. Dr. Robert F. Kaiko, OxyContin's inventor, testified at trial that he had done no clinical studies and had no evidence

to support Purdue's claim that the drug was effective in low dosages for 90 percent of patients. Purdue admitted that Dr. Kaiko's "discovery" was not supported by evidence or clinical studies. Internal company documents revealed that in 1993 Purdue executives concluded that the company's representations to the P.T.O. "weren't anywhere close" to being proved and were "clearly Bob Kaiko's vision."

65. The Court determined that "[t]he record as a whole reflected a clear pattern of intentional misrepresentation of a material fact: Purdue knew that it did not have 'scientific proof' of its 'discovery,' yet repeatedly asserted its 'discovery' to the PTO in precise, quantified, and past-tense language." 2004 WL 26523 at *27.

G. Defendants' Deceptive Marketing Practices

66. After Purdue fraudulently obtained its patents, Purdue began promoting OxyContin with a sales force of approximately 300 representatives in its Prescription Sales Division. Through aggressive marketing efforts, many of which are the subject of governmental scrutiny, OxyContin quickly became Purdue's dominant revenue source.

67. To further increase OxyContin demand, market share, and revenue, Purdue entered a co-promotion agreement with Abbott in 1996. Pursuant to that agreement, Abbott provided at least another 300 representatives, doubling the total OxyContin sales force. By 2002, 1,067 Abbott and Purdue sales representatives were promoting OxyContin actively to hospital-based anesthesiologists and surgeons, major hospitals, medical centers, and freestanding pain clinics nationwide, including in New York City. Such targeted promotion was instrumental in entrenching OxyContin at supra-competitive prices. In 2001, Purdue spent $149 million on its field representatives and paid Abbott more than $90 million for its OxyContin efforts.

68. The General Accounting Office ("GAO") has found that in marketing OxyContin, the promotional videos of the defendants made unsubstantiated claims and

minimized the dangers and addictiveness associated with the pain relief drug. The GAO also found that in 1998, Purdue failed to submit one of the promotional videos to the FDA for review, as required, when it circulated it to thousands of doctors.

69. The aggressive and fraudulent marketing of OxyContin, coupled with the drug's undisclosed addictiveness, expanded the monopoly power defendants had over its pricing and furthered the drug's sales, thereby unjustly enriching Purdue. Further, the profits that Abbott obtained from the co-promotion agreement with Purdue derived themselves from monopoly rents that Purdue enjoyed in violation of antitrust laws. Therefore, Abbott also was unjustly enriched through its co-promotion agreement with Purdue.

H. Defendants' Fraudulent Concealment

70. Throughout the course of the proceedings before the PTO and through the litigation of the infringement actions, Purdue knowingly, willfully and fraudulently has concealed and is concealing the true facts about their misrepresentations to the PTO in order to wrongfully obtain the '912, '042 and '295 patents and to wrongfully prevent and discourage lawful competition with their brand name product OxyContin.

71. Purdue has vigorously defended its fraudulent patents to preserve its monopoly power over the relevant market and with its marketing agent Abbott has aggressively promoted OxyContin and taken all steps possible to increase and maintain market share. This fraudulent concealment prevented the City of New York from learning the truth about defendants' illegal conduct until the January 5, 2004 ruling of this Court.

COUNT I

FOR DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTION 2 OF THE SHERMAN ACT (Against Purdue)

72. The City realleges and incorporates the preceding paragraphs as if fully set forth herein.

73. As described above, Purdue knowingly and willfully engaged in a course of conduct designated to improperly obtain and extend its monopoly power in the relevant market. This course of conduct included, *inter alia*, the following acts: (i) intentionally submitting false patent information to the FDA and PTO; (ii) intentionally making fraudulent omissions and statements to the FDA and PTO; (iii) prosecuting baseless patent litigation against generic competitors; (iv) maintaining meritless defenses against the counterclaims by Endo and Teva; (v) aggressively and fraudulently marketing OxyContin; and (vi) charging and reporting monopolistic prices for OxyContin. The result of Purdue's unlawful conduct has been to obtain and extend its monopoly in the relevant market for OxyContin and its bioequivalents, and to charge unlawful monopolistic prices for OxyContin.

74. Purdue's infringement actions against Teva and Endo are sham litigations. The suits are objectively baseless given Purdue's fraud on the PTO and because Purdue seeks only to prevent generic competitors from marketing less-expensive generic versions of OxyContin that would compete with the brand-name product.

COUNT II

FOR COMPENSATORY AND MULTIPLE DAMAGES UNDER NEW YORK GENERAL BUSINESS LAW § 340 (The Donnelly Act) (Against Purdue)

75. The City realleges and incorporates the preceding paragraphs as if fully set forth herein.

76. Purdue's conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as prohibited practices and unconscionable conduct under New York's antitrust statute, General Business Law § 340 (the "Donnelly Act").

77. As a result of the conduct described above, the City has sustained and will continue to sustain substantial losses and damage in its businesses and property in that, *inter alia*, the Medicaid program has been and is deprived of the ability to purchase less expensive, generic versions of oxycodone hydrochloride-cr, and has been and is paying higher prices for oxycodone hydrochloride-cr products than it would have but for defendants' improper actions.

COUNT III

VIOLATION OF NEW YORK SOCIAL SERVICES LAW § 145-b OBTAINING PUBLIC FUNDS BY FALSE STATEMENTS (Against Purdue)

78. The City realleges and incorporates the preceding paragraphs as if fully set forth herein.

79. New York Social Services Law § 145-b (1) (a) provides:

> It shall be unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payment from public funds for services or supplies furnished or purportedly furnished pursuant to this Chapter [*i.e.*, the Social Services Law].

80. By engaging in the acts and practices described above, defendants have knowingly made false statements and representations to the PTO, to the FDA, and to non-party publishers upon whom Medicaid payors rely for publishing Average Wholesale Prices, such as the publishers of the *Blue Book* and *Red Book*.

81. Purdue's intentional false statements to the PTO were made for the express purpose of preventing generic oxycodone hydrochloride-cr from entering the market. Purdue thereby extended its monopoly over oxycodone hydrochloride-cr and its ability to report and/or charge unlawful monopolistic prices for this product.

82. Defendants made those statements on their own behalf and on behalf of others, knowing and expecting that its fraudulent representations would result in the overpayment of public funds for OxyContin by the New York State Medicaid program.

83. The Average Wholesale Prices for oxycodone hydrochloride-cr charged to Medicaid as a result of false statements by defendants constituted and continue to constitute fraudulent reports of data which serve as the basis for claims or rates of payment, as defined in Social Services Law § 145-b (1) (b).

84. Purdue attempted to and did obtain public funds on behalf of itself or others that were used to reimburse entities from which Purdue sought payment, as defined in Social Services Law § 145-b (1) (c).

COUNT IV

FOR DAMAGES, INJUNCTIVE AND DECLARATORY RELIEF UNDER GENERAL BUSINESS LAW § 349 (Against All Defendants)

85. The City realleges and incorporates the preceding paragraphs as if fully set forth herein.

86. Defendants' conduct described herein violates New York's unfair and deceptive trade practices statute, General Business Law § 349.

87. General Business Law § 349 makes unlawful "deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state."

88. By virtue of the deceptive conduct alleged above, defendants engaged in consumer-oriented deceptive acts and practices within the meaning of Gen. Bus. L. § 349 that damaged the public and the City by overcharging for OxyContin and preventing the entry of lower priced generic alternatives to the market.

89. New York's Medicaid statute expressly states that "[m]edical assistance for needy persons is hereby declared to be a matter of public concern and a necessity in promoting the public health and welfare." New York Soc. Serv. L. § 363. Defendants' intentional deceptive conduct with respect to OxyContin is in direct contravention of this statutorily established public policy.

90. Defendants' conduct violates General Business Law § 349 in that:

(a) Purdue failed to disclose that the City's payment of an inflated AWP for OxyContin results from the fact that defendants have, through fraud, unlawfully extended their monopoly of oxycodone hydrochloride-cr; and

(b) Purdue violated federal and state antitrust statutes and Medicaid fraud statutes through its anticompetitive conduct and imposition of wrongfully charged monopolistic prices. These statutory violations serve as predicates for violation of Gen. Bus. L. § 349; and

(c) Defendants engaged in aggressive and fraudulent marketing practices designed to increase market share for OxyContin at monopoly prices.

91. The wrongful conduct alleged in this Complaint occurs nationwide, including in New York City and occurs in the OxyContin transactions that take place in New York City. Defendants specifically market and distribute OxyContin in New York City, and publish inflated AWPs for OxyContin that defendants know will be used in New York to calculate Medicaid reimbursement.

92. The intentional wrongful conduct described here occurs and continues to occur in the course of defendants' business and has caused great harm to all who pay for OxyContin, including the City.

93. The City forseeably has overpaid millions of dollars for OxyContin as a result of defendants' intentional misconduct. The City's damage is a direct and proximate result of defendants' fraud.

94. Plaintiff has been injured in its business or property by reason of defendants' antitrust violation alleged in this Court.

COUNT V

FOR RESTITUTION, DISGORGEMENT AND CONSTRUCTIVE TRUST FOR UNJUST ENRICHMENT BY DEFENDANTS
(Against All Defendants)

95. The City realleges and incorporates the preceding paragraphs as if fully set forth herein.

96. As a result of their unlawful conduct described above, defendants have been and will continue to be unjustly enriched. Purdue's unlawful acts include improperly listing its patents in the *Orange Book*; submitting fraudulent misrepresentations to, and concealing material facts from the PTO; filing and pursuing baseless patent infringement actions; and maintaining baseless defenses to counterclaims, all at the expense of the City. Defendants have used Purdue's fraudulently-obtained patents to create and maintain an unlawful monopoly

for the drug OxyContin, to aggressively increase market share for the drug and to charge unlawful monopolistic prices.

97. Defendants have been unjustly enriched, to the detriment of the City by the receipt of, at a minimum, unlawfully inflated prices and illegal monopoly profits on their sales of OxyContin.

98. Defendants have benefited from their unlawful acts and it would be inequitable for defendants to be permitted to retain any of their ill-gotten gains resulting from the overpayments for OxyContin made by Plaintiff.

99. Plaintiff is entitled to the amount of defendants' ill-gotten gains resulting from defendants' unlawful, unjust and inequitable conduct. Plaintiff is entitled to the establishment of a constructive trust consisting of defendants' ill-gotten gains from which the City may make claims based on the City's payments for OxyContin under Medicaid.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff the City of New York prays that:

(a) the conduct alleged herein be declared, adjudged and decreed to be in violation of Section 2 of the Sherman Act;

(b) the conduct alleged here be declared, adjudged and decreed to be in violation of New York's General Business Law § 340 (the Donnelly Act);

(c) the conduct alleged here be herein declared, adjudged and decreed to be in violation of New York General Business Law § 349;

(d) the conduct alleged here be declared, adjudged and decreed to be in violation of New York Social Services Law § 145-b;

(e) The City of New York be awarded damages and, where applicable, treble, multiple, and other damages, according to New York General Business Law §§ 340 and 349 and New York Social Service Law § 145-b, plus interest;

(f) The City of New York recover the amounts by which defendants have been unjustly enriched, plus interest;

(g) Defendants be enjoined from continuing to charge unlawful monopoly prices for OxyContin and continuing the illegal activities alleged herein;

(h) Plaintiff recover its costs of suit, including reasonable attorneys' fees and expenses as provided by law; and

(i) Plaintiff be granted such other and further relief as the Court deems just and necessary.

JURY DEMANDED

Plaintiff demands a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues so triable.

Dated: May __, 2004

Respectfully submitted,

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